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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,963	08/15/2006	Paolo Alberto Veronesi	IPU1954-009	8586

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STANDLEY LAW GROUP LLP
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EXAMINER	
LOVE, TREVOR M	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
09/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,963	VERONESI, PAOLO ALBERTO	
	Examiner	Art Unit	
	TREVOR LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-3,6,8-12 and 14-31* is/are pending in the application.

5a) Of the above claim(s) *2,15 and 18-31* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3,6,8-12,14,16 and 17* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/31/2011 has been entered.

Claims 1-3, 6, 8-12, and 14-31 are pending.

Claims 2, 15, and 18-31 are withdrawn.

Claims 1, 6, 8, 10, 12, 16, and 17 are currently amended.

Claims 1, 3, 6, 8-14, 16, and 17 are currently under consideration.

Withdrawn Rejections and/or Objections

The rejection of claim 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's cancellation of said claim.

The rejection of claims 1, 3, 5-12, 14, 16, and 17 under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) is withdrawn in view of Applicant's amendments to the claims.

The rejection of claims 1, 3, 5-14, 16, and 17 under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3, 5-12, 14, 16, and 17 above, and further in view of Lundberg et al (U.S. Patent number 6,013,281, patent issued Jan. 11, 2000) is withdrawn in view of Applicant's amendments to the claims.

The rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) in view of Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference) as applied to claims 1, 3, 5-12, 14, 16, and 17 above, and further in view of Hunter et al (U.S. Patent number 6,159,459, patent issued Dec. 12, 2000) is withdrawn in view of Applicant's cancellation of said claim.

New Grounds of Rejection

Claim Objections

Claims 12 and 17 are objected to because of the following informalities: Said claims recite the term "microliters" (claim 12 recites it twice), however, said term is improperly spelled as "microlitres". Appropriate correction is required.

The instant claims improperly have a phrase inserted between claims 28 and 29. Said phrase reads "This paper is filed in response to the Office Action mailed

on 12 May 2010, making non-final rejection of the claims." It is believed that this is merely a clerical error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6, 8-12, 14, 16, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims filed 01/18/2011 have introduced NEW MATTER into the claims.

As presently amended claim 1 recites four (4) separate new matter issues.

1) Newly amended claim 1 recites that the composition comprises "a biologically compatible *base*" (emphasis added). Thus, the claim broadly encompasses the use of any base. The specification only provides support for the term "buffer".

2) Newly amended claim 1 recites that the upper limit of the pH range is "6.9". Thus, the claim provides an upper limit which was not previously presented or supported in the specification. The specification only supports an upper limit of 8.0 and 7.5.

3) Newly amended claim 1 recites that the lower limit of the flurbiprofen quantity is “2.0 mg/ml”. Thus, the claim provides a lower limit which was not previously presented or supported in the specification. The specification only supports a lower limit of 1.5 mg/ml.

4) Newly amended claim 1 recites that the upper limit of the flurbiprofen quantity is “4.0 mg/ml”. Thus, the claim provides an upper limit which was not previously presented or supported in the specification. The specification only supports an upper limit of 8.0 mg/ml.

The response did not point out where support for currently amended claim 1 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 (“Applicant should therefore specifically point out the support for any amendments made to the disclosure.”).

As presently amended, the claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the presently amended claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the

specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Claims 3, 6, 8-12, 14, 16, and 17 are rejected for depending from claim 1 which comprises new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6, 9, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naaijkens et al (INABIS 2000) in view of Stalker et al (Pharmaceutical Research).

Naaijkens teaches an oral and or topical formulation comprising flurbiprofen, meglumine (N-methylglucamine), water, a viscosity agent (hydroxyethylcellulose), and a preservative (Kathon CG) (see entire document, for instance, second table, page 2 of

7). Said composition has a pH of 6.8 (see entire document, for instance, first paragraph under “Discussion” on page 6 of 7). Naaijkens teaches that meglumine is present to obtain a composition which is clear and transparent, and allows for the flurbiprofen to the dissolved when utilized in equimolar amounts (see entire document, for instance, first paragraph under section "Explanatory note to the use of meglumine (N-Methylglucamine) and Kathon CG®" on page 2 of 7).

Naaijkens, while teaching the presence of flurbiprofen, fails to directly teach that the composition comprises the NSAID in an amount of between 2.0 to 4.0 mg/ml as newly required in claim 1. Further Naaijkens, while teaching the presence of meglumine, does not teach the instantly claimed amount meglumine.

Stalker teaches a solution of flurbiprofen in an amount of 2.5 mg/ml (see entire document, for instance, Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize flurbiprofen in an amount of 2.5 mg/ml in the composition of Naaijkens. One would have been motivated to do so since Stalker teaches that 2.5 mg/ml is a useful dosage for mouthwash compositions. There would be a reasonable expectation of success since Naaijkens and Stalker are both directed to oral formulations comprising flurbiprofen, wherein it is known to vary the amount of an active agent depending on the intended use, size of the patient, and severity of the condition being treated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize about 2 mg/ml of meglumine in the composition of

Naaijkens. One would have been motivated to do so since Naaijkens teaches that meglumine is utilized in an equimolar amount to the flurbiprofen present, wherein when 2.5 mg/ml of flurbiprofen is utilized the equimolar amount of meglumine is about 2 mg/ml.

With regard to the use of either the racemate or the R or S enantiomers, it is noted that the composition is necessarily in one of said formations since said options listed in claim 3 cover all possible formations.

With regard to the composition being “sprayable” as required in instant claim 1, and that the composition be in the form of “a mouthwash for spraying, with a dispensing volume for each unit dose of from 100 microlitres (0.1 ml) to 300 microlitres (0.3 ml)" as required in claim 12, and 200 microliters as required in claim 17, it is noted that the composition of Naaijkens in view of Stalker is capable of being sprayed, and capable of being sprayed in said amounts. As such, the limitations have been met.

Claims 8, 10, 11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naaijkens et al (INABIS 2000) in view of Stalker et al (Pharmaceutical Research) as applied to claims 1, 3, 6, 9, 12, 16, and 17, and further in view of Pinza (WO 03/094905, Published Nov. 20, 2003) (IDS reference) and Caldwell (U.S. 5,183,829, Patent issued Feb. 2, 1993) (IDS reference).

The teachings of Naaijkens and Stalker are set forth above.

Naaijkens in view of Stalker, while teaching the presence of a preservative, fails to directly teach the instantly claimed preservatives. Further, Naaijkens in view of

Stalker, while teaching the presence of excipients such as HCl, hydroxyethylcellulose, and Kathon CG, fails to directly teach the presence of xylitol. Finally, Naaijkens in view of Stalker, while teaching that the composition can be oral and topical, and can be in the form of a mouthwash, fails to directly identify that the composition can be in the form of a spray.

Pinza teaches an aqueous mouthwash or oral spray (see entire document, especially page 3, lines 22-23 and claim 1). Said composition comprising diclofenac (see entire document, for instance claim 1). Said composition further comprises sweeteners such as sodium saccharinate, sorbitol, xylitol to increase palatability of the solution (see entire document, for instance claim 3 and page 2, lines 18-20). Said composition further comprises a preserving agent, specifically sodium benzoate, methyl p-hydroxybenzoate, or propyl p-hydroxybenzoate (see entire document, for instance claim 4). Said, for instance, sodium benzoate is exemplified as being present in an amount of 5 mg/ml (see entire document, for instance, example 1).

Caldwell teaches an oral composition comprising a non-steroidal anti-inflammatory, specifically, either diclofenac, flurbiprofen, naproxen, or ketoprofen (see entire document, for instance claims 1 and 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize additional preservatives such as sodium benzoate in the composition of Naaijkens. One would have been motivated to do so since Naaijkens teaches the use of preservatives, wherein the combination of components known in the art as being useful for the exact same purpose is obvious. It is noted that MPEP

2144.05 states: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

It further would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize xylitol in the composition of Naaijkens. One would have been motivated to do so since Pinza teaches that xylitol and other sweeteners increase the palatability of the solution. There would be a reasonable expectation of success since both Naaijkens and Pinza are teaching that the composition is useful in the mouth, wherein Pinza identifies that xylitol can increase palatability.

Finally, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize composition of Naaijkens in view of Stalker as a topical oral mouthwash spray. One would have been motivated to do so since Naaijkens teaches that the composition is an oral and/or topical formulation, wherein Stalker teaches that formulations of the composition of Naaijkens are useful as mouthwashes, wherein Pinza teaches topical oral mouthwash sprays comprising NSAIDS such as diclofenac, wherein Caldwell identifies that diclofenac and flurbiprofen are both NSAIDs which can be interchanged. It is noted that MPEP 2144.06(II) states "[a]n express suggestion to substitute one equivalent component or process for another

is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)".

It is further noted that a spray composition necessarily requires the presence of a dosing pump. Therefore, since the composition of Naaijkens in view of Stalker, Pinza, and Caldwell is a spray, the composition would necessarily require a dosing pump for use.

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/SHARMILA G. LANDAU/

Supervisory Patent Examiner, Art Unit 1611